Remarks

In the interest of clarity, the paragraph numbers hereafter match the paragraph numbers in the Office Action.

3-4. As an initial matter Applicant thanks the Examiner for indicating that some of the claims are allowed and that others would be allowed is rewritten to be in independent form. Here, however, Applicant is confused as some of the claims are indicated as allowed and also objected to. In this regard, the Office Action indicates that claims 194-200 and 221-222 are each both allowed and objected to. Applicant believes the Examiner intended to indicate that claims 194-200 and 221 and 222 where objected to. Therefore Applicant has amended claim 194 to place that claim in independent form. The balance of the objected to claims depend from claim 194 and therefore should be in condition for allowance.

Also notes that the claim amendments include cancellation of language related to collection of data associated with a physician that is not needed.

5-6. The Office Action rejected each of claims 1, 22, 201, 212, 213, 217, 219, 220, 231 and 232 as obvious over Gombrich in view of Hamner. Applicant has amended claim 1 to more specifically point out the present invention and in a way which more clearly distinguishes over the prior art.

As an initial matter Applicant points out that some of the elements the Examiner has indicated are taught by the prior art in the past and that the Examiner continues to indicate are missing clearly are not taught by the prior art. Here it may be that the Examiner is not clearly articulating how the references are being applied. If this is the case Applicant requests that if the Examiner maintains the current rejections, the Examiner please more clearly describe how the cited references teach the claim

limitations. If the Examiner's rejections are unclear or cryptic it is difficult for Applicant to respond in a meaningful way. For instance, with respect to the claim 1 step of associating a controller with a medical device so that the controller can communicate with the medical device, the Office Action cites Gombrich col. 2, lines 36-45. While the cited section contemplates associating a hospital item (e.g., a medication) with a patient, absolutely nothing in the cited material contemplates or even remotely suggests associating a device with a controller or associating so that a controller can communicate with a medical device. This short coming and other missing teachings are described in greater detail below.

With respect to claim 1, claim 1 is provided so that a system user can intuitively select a medical device in the user's vicinity to be associated with a specific controller to perform a specific medical task. For instance, where a user wants to use a specific IV pump to administer a fluid to a patient, the user can simply associate the specific pump with a controller to facilitate delivery. Here, while quick association is facilitated, the entire process is not completely automated and at least one step is manual so that a user can control the process and add intelligence where needed. To this end, for instance, where there are five IV pumps in a patient's room, a user can select one of the five pumps by manually placing a portable data collector proximate a device identifier associated with a specific pump and obtaining device identifier information from that specific pump. Thereafter the controller and specific pump are associated using the device identifier information and the controller can communicate with the pump or other medical device.

Consistent with the above comments, amended claim 1 now requires, among other things:

(1) obtaining device identifier information from the device identifier <u>while a portable data collector is proximate the device identifier</u> where the obtained

information identifies a medical device within a communication network (i.e., a device identifier that identifies a device within a communication network);

(2) transferring the device identifier information to a controller;

(3) using the identifier information to associate the controller with the medical device and

(4) causing the controller to send a communication to the medical device (i.e., a controller with communication capabilities and a medical device that is capable of receiving communications on a network).

The Office Action correctly points out that Gombrich fails to teach or suggest a device identifier that includes information that can be used to communicate with an associated medical device or causing a controller to send a communication to the medical device.

In addition, however, the Office Action erroneously indicates that other claim 1 steps described above are taught by Gombrich. Applicant states here in no uncertain terms that none of the steps above is taught or suggested by Gombrich. For instance, if Gombrich fails to teach device identifier information, how can Gombrich teach or even remotely suggest using such information to associate a controller with a medical device or that association can be performed so that there can be communication between a controller and a medical device. In this regard the Office Action cites Gombrich col. 2, lines 36-45. Instead of teaching a controller-to-medical device association step, col. 2, lines 36-45 teach that items can be related to specific patients via patient identifiers on items and a patient and that a verification process can be performed when a patient tag and an item tag are both obtained. For instance, patient ID tags identifying a specific patent can be provided for a patient and on hospital items and where the tags match, an association can be made.

Here, a patient clearly is not a controller and therefore association with a patient cannot be read as an association with a controller. In addition, association with a patient in Gombrich is not so that a controller can communicate with a medical device.

Again, Gombrich fails to teach a controller that communicates with medical devices so how could association be for communication purposes.

Turning to Hamner, Hamner's Background section recognizes that computer networks have become massive and that it is difficult at best for network administrators to keep track of all components linked to a network. For instance, in the case of local area networks or the like there may be several thousand computers and other devices linked to a network and tracking linked components and the tasks that they can perform is particularly complicated. To deal with massive networks, Hamner teaches a system that can be used to identify all components that are linked to a network and to identify all tasks that can be performed by the network components (see col. 1, lines 47-50). Here, a discovery manager periodically polls a network to identify networked components and tasks that can be performed by each component (see col. 6, lines 14-17). For instance, where there are 200 IV pumps linked to a network and one managing server, the server may run polling software that identifies all 200 pumps and tasks that each pump can perform. In Hamner, once network components are remotely identified, a system user can manually select one of the components to perform a task (see col. 4, lines 40-46) via a user interface device.

Thus, while the present invention allows a user that is present near a specific medical device to manually select the specific device for association with a controller to facilitate communication, Hamner teaches a system that is the exact opposite where network linked devices are discovered remotely (e.g., by a NIC (801, 802, 803 804, 805, 806, 811) with an IP address and MAC address) and a user is presented an interface that shows all linked components and tasks that each component can perform. In Hamner where the primary invention is centered on remote identification and association of components with other components, it would make no sense to include a system where association of components requires a manual step where a user is proximate a device to be controlled. For instance, assume that 200 separate computers

linked to a network can each perform a required task. Here, Hamner would have the manager identify all 200 computers that can perform the task and would provide a list of 200 options for selection to a user. In contrast, in the case of claim 1, assuming a user wanted to associate a controller with the 153rd computer out of 200 linked computers. The user would have to travel to the location of the 153rd computer, proximate to a specific patient, to manually obtain the device identifier information which would then be transmitted to the managing server so that association could be made. Manual association in Hamner would be absurd at best. For this reason Hamner should not be combined with any reference that requires manual collection of data to facilitate association of a device with a controller.

In addition, even if Hamner and Gombrich were to be combined, the combination would not include all of the limitations of claim 1. To this end, Hamner could be used to obtain all linked component information and to identify tasks that can be performed by each linked component. Thereafter, Gombrich could be used to obtain patient identifying information from a patient tag and an IV bag tag so that a processor could determine if the IV fluid is intended for the user. Where the fluid is intended, Hamner could at best be used to remotely select one of 200 IV pumps to deliver the fluid to the patient and then the fluid could be delivered. In the combination there is no step of obtaining device identifier information for the IV pump with a data collector proximate the IV pump or using the manually obtained information to associate a controller with the pump to facilitate communication.

For at least the above reasons Applicant believes amended claim 1 and claims that depend there from are non-obvious over the cited art and requests that the current rejection be withdrawn.

With respect to the other rejections, Applicant notes that many of the other

pending claims are clearly different than and non-obvious over the prior art cited. Hereafter, Applicant presents arguments regarding only a subset of the dependent claims that are non-obvious but has elected not to provide arguments regarding the other claims in the interest of shortening this response and because Applicant is clear that the current amendments should render the pending claims non-obvious over the cited art.

With respect to claim 22, claim 22 requires that the medical device and the controller perform a health safety function. The Office Action cites col. 15, line 9 to col. 16, line 2 as teaching this limitation. The cited section of Gombrich simply teaches a system wherein a portable data collector is used to obtain patient ID information from a patient tag and hospital item tags, compares the obtained information and, based on the comparison, the data collector indicates if there is or is not a match. Thus, here, the portable data collector performs the process, not the medical device and a controller. In fact in claim 22 (as in claim 1), the medical device and the controller are separate from the data collector and therefore a system like Gombrich that teaches a data collector that performs a process does not read on or obviate a system where two other completely separate components (i.e., the medical device and the controller) perform a process.

For at least this additional reason claim 22 is not obviated by the cited art and Applicant requests that the current rejection be withdrawn.

With respect to claim 213, claim 213 limits claim 1 by requiring that, among other things, the controller obtain medication control information and use the control information to control the medication device. As discussed above and at length in prior Office Action responses Gombrich never communicates back to a medical device that is associated with device identifier information in any way so clearly Gombrich cannot teach that a controller some how controls a medical device as required by this claim.

Turning to the section cited in the Office Action, the cited section simply teaches that a portable data collecting terminal may communicate with a base station. Here, the portable device is not a medical device and instead is akin to the portable device in claim 1. Thus, the Examiner has confused a portable device with a medical device which are clearly two separate components of the claims.

For at least this additional reason claim 213 is not obviated by the cited art and Applicant requests that the current rejection be withdrawn.

Claim 217 further limits claim 1 by requiring the step of associating the controller with a patient. Gombrich fails to teach or suggest this limitation. The cited section of Gombrich simply teaches that patient labels are printed out that can be attached to hospital items to associate the hospital items with the patent at a later time. Here the hospital items contemplated do not include a controller (see exemplary items at col. 8, lines 31-42).

For at least this additional reason claim 217 is not obviated by the cited art and Applicant requests that the current rejection be withdrawn.

Claim 219 requires the step of identifying two times when data obtaining events occur and when the two times are sufficiently different (i.e., outside a threshold), performing a health safety function. These two events are always to be completed within a time limit, not the coincidentally timed, but independent events of Grombrich. The sections of Gombrich cited as teaching these limitations clearly does not teach these limitations. To this end, the col. 15 section cited has nothing to do with recording times when data is collected. The only part of col. 15 that discusses time at all is at line 14 where Gombrich teaches that the times medication is administered are stored. Here, administration time may have absolutely nothing to do with a time when data is collected. In col. 16, the cited section describes that the system may indicate when a medication is late by comparing a time when a medication is prescribed for delivery to a current time. Here, again, the current time and the time when a medication is

prescribed to be delivered will usually have nothing to do with times when data is collected.

For at least this additional reason claim 219 is not obviated by the cited art and Applicant requests that the current rejection be withdrawn.

Regarding claim 220, claim 220 requires that the two data collection times be selected from a specific list. The Office Action indicates support for only two of the listed times and one of the supposed supporting sections in fact does not support the claimed limitation. To this end, while Gombrich teaches obtaining information from a patient identification device. Absolutely nothing in Gombrich teaches or suggests that the time at which patient identifying information is obtained from a patient tag is stored for any purpose. To the extent the Examiner maintains this rejection Applicant requests that the Examiner clearly indicate where Gombrich teaches this limitation instead of citing a large section of the specification.

For at least this additional reason claim 219 is not obviated by the cited art and Applicant requests that the current rejection be withdrawn.

7. The Office Action rejected each of claims 2-20, 193, 202, 203 and 208-211 as obvious over Gombrich in view of Hamner and the Examiner's official notice. Applicant traverses this rejection with respect to many of the claims.

Regarding claim 5, claim 5 further limits claim 1 by requiring the step of, in response to the communication, causing a medical device to perform a safety function. Applicant is clear Gombrich fails to teach or suggest this limitation. The section of Gombrich cited in the Office Action includes col. 15, line 49 through col. 16, line 2 which teaches that a hand held data collector may illuminate an LED or the like to indicate a safety condition. Causing a data collector to indicate a condition is clearly different than causing a medical device to perform a safety function – the medical device and the data collector are two completely different components. Applicant points out that this

distinction is not a matter of designer choice and that a completely different affect results from the claim 5 invention. To this end, where a medical device performs a function the function may be to completely inhibited as a safety precaution. A similar effect cannot be performed where a portable data collector is to perform a safety function.

For this additional reason Applicant is clear claim 5 is non-obvious over the cited art and requests that the current rejection be withdrawn.

Claim 6 requires activating an indicator on the medical device. Again, Gombrich teaches activating an indicator on a data collector, not on a medical device. A data collector is a completely different component than a medical device. For this additional reason Applicant is clear claim 6 is non-obvious over the cited art and requests that the current rejection be withdrawn.

Claim 7 requires that the medical device include a transmitter and causing the transmitter to transmit a response communication. The cited section of Gombrich teaches a portable data collector that includes a transmitter, not a medical device that includes a transmitter. For this additional reason Applicant is clear claim 7 is non-obvious over the cited art and requests that the current rejection be withdrawn.

Claim 193 requires that the step of obtaining the device identifier information includes reading a bar code. While Gombrich teaches reading a bar code, the bar code that is read clearly does not include information that can be used to communicate with the medical device. In fact, as indicated above, Gombrich fails to teach even a single instance where a medical device associated with obtained information can be communicated with in any way. For this additional reason Applicant is clear claim 193 is non-obvious over the cited art and requests that the current rejection be withdrawn.

Claim 202 further requires using a medical device address to communicate with the medical device. Again, while Gombrich contemplates communicating with a portable data collector, Gombrich fails to teach or suggest communicating with a medical device that is associated with device identifier information or any form of communication with a medical deivce having receiving capabilites . Again, claim 1 requires a portable data collector that is separate from a medical device and therefore the data collector in Gombrich cannot read the medical device. For this additional reason Applicant is clear claim 202 is non-obvious over the cited art and requests that the current rejection be withdrawn.

Claim 203 requires that a medical device communicate by transmitting to a controller. Gombrich's portable data collector is not a medical device as discussed above. For this additional reason Applicant is clear claim 203 is non-obvious over the cited art and requests that the current rejection be withdrawn.

8. The Office Action rejected each of claims 21, 23, 24, 206,214, 215 and 216 as obvious over Gombrich in view of Hamner and Kerns. Applicant traverses many of these rejections for additional reasons.

Claim 21 requires that the medical device be an infusion pump. In the case of an infusion pump or any other medical device that is intended to be reused multiple times, the pump is typically only temporarily to be associated with a patient and thereafter is reused with other patients. Here it would be highly unlikely that a patient identifier tag associating a pump with a single patient would be attached to or associated with a pump. For this reason, while Kerns teaches multiple pumps, placement of a patient specific tag as in Gombrich on one or more pumps would be highly unlikely and in general would not make sense. Even so the RF transmitter units 220 of Gombrich do not a receiver capability. Thus, no one of skill in the art would be motivated by

Gombrich or Kerns to combine the teachings. For this additional reason Applicant is clear claim 21 is non-obvious over the cited art and requests that the current rejection be withdrawn.

Other non-obvious claims exist but are not being presented here in the interest of shortening this response and in light of the amendments described above.

Applicant has added new claims 233-238 which are supported by the originally filed specification.

Applicant has introduced no new matter in making the above remarks and amendments. In view of the above remarks and amendments, Applicant believes claims 1-24, 193-217 and 219 through 238 of the present application recite patentable subject matter and allowance of the same is requested. No fee in addition to the fees already authorized in this and accompanying documentation is believed to be required to enter this amendment, however, if an additional fee is required, please charge Deposit Account No. 17-0055 in the amount of the fee.

Respectfully submitted,

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